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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/056,588

01/23/2002

Jennifer L. Pavlovic

19369/116/101

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07/27/2004

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,588

Applicant(s)

PAVLOVIC, JENNIFER

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-55 is/are pending in the application.
- 4a) Of the above claim(s) 32-43, 48 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-47 and 49-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/30/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. Newly submitted claims 32-43 and 55 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally examined invention [see “Response” dated January 14, 2004] was a product and newly added claims 32-43 are a *process of making* a distal protection device. The inventions are distinct because the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). For example, the distal protection device *as originally elected* could be made by weaving instead of by electrospinning.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-43 and 55 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Additionally, claim 48 is directed to a withdrawn species. Applicant elected “Species B: metallic frame” (as opposed to the non-metallic frame) in “Response” dated January 14, 2004. Therefore, once again, since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 48 is also withdrawn from consideration as

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being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. As a word of introduction, Applicant is directed to MPEP Chapter 2100; section 2113 “Product-by-Process Claims.” In that section, the MPEP is clear that “the patentability of the product does not depend on its method of production.” Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture. In Applicant’s response to this office action, Applicant should rewrite the claims putting the process and product in different groups. Each set of groups should start with an independent claim.
3. Claims 44, 46, and 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,610,077 to Hancock et al. Regarding Claims 44 and 54, Hancock discloses an emboli filter (70), for catching debris in a blood vessel. With reference to *Figure 4A*, Hancock discloses two flexible wires (72 and 74) oriented to define a perimeter. These wires are quite thin and can therefore be

flexed with minimal force applied. These wires form a *frame*. Hancock also discloses a fiber matrix (76) [Column 7, lines 52-54] secured to the frame. The fibers are spun (wrapped) around the two wires (72 and 74) criss-cross to form many spaces, interstices and pores between them. The filter (70) is carried on a guide wire (28) [Column 7, lines 44-47]. The filter is collapsible and expandable to engage the walls of the lumen [Column 8, lines 1-13].

4. Regarding Claim 46, Hancock's wire frame has a larger diameter than the fibers (76) [Fig. 4A].
5. Regarding Claim 52, Hancock's wire (24) is said to have a diameter of 0.003 inches, and is the same component as wire (70) [Column 7, lines 3-7; compare Figure 1B with Figure 4A].
6. Regarding Claim 53, Hancock discloses a guidewire (28) shown in Fig. 4A with a filter (70) at its distal end.
7. Claims 44, 47, 49, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,540,768 to Diaz et al. Regarding Claim 44, Diaz discloses an emboli trap with a wire frame. The wire frame has a plurality of wires (S), which define a circular perimeter [Fig. 24]. Each segment (S) can be considered a separated wire segment. Wires (50/51) in Figure 3 also define a circular perimeter. Any cut taken from conical filter shown in Figures 3-5b will be a circle, and wire (50) will intersect that circle.

Diaz discloses a fiber matrix ("filter membrane 20") secured to the wire frame [Column 5, lines 22-28]. Diaz's fiber matrix allows blood to pass, but not

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particulate matter [Column 5, lines 22-28]. Figure 5A shows the filter in its collapsed configuration, and Figure 5B shows it in its expanded configuration.

Diaz's filter is carried by a guide wire (10) [Column 5, lines 3-10].

Regarding the method of manufacture of the filter ["plurality of wires on which said fibers are spun to form a matrix"], Diaz's filter is capable of being manufactured in this way.

8. Regarding Claims 47 and 49, Diaz's wire frame (50/51) is metallic [Column 5, lines 19-21]. They can also be made of nitinol [Column 5, lines 43-47]. Wires (S) are also assumed to be metallic, because all of the other structural support elements (50/51) are disclosed as being made out of stainless steel or nitinol.
9. Regarding Claim 51, the fibers of Diaz's filter are made out of polyurethane [Column 8, lines 36-39].
10. Claim 45 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 6,540,768 to Diaz et al. Regarding Claim 45, the difference between 50% and "about 80%" is not very significant, and would be an obvious matter of design choice to alter the number of holes or size of the holes to increase the open area slightly. Applicant should note in Column 8, lines 36-52 that Diaz gives a range for each measurement (hole size and spacing between holes) which varies widely.

11. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,540,768 to Diaz et al. Regarding Claim 50, Diaz discloses that his filter can either be a fabric (consisting of fibers) or a non-fabric material with holes in it [Column 5, lines 36-40]. Diaz does not describe how thick the fibers of his fabric are, but the alternative embodiment described in Column 8, lines 36-51, Diaz describes pores having a size of 100 micrometers. Thus the fibers used to form a fabric having pores of this size would have to have a diameter on the order of 10 microns. The distance between the holes of the described embodiment is 70 micrometers (1.4 times 50 micrometers) (at the smallest) [Column 8, lines 42-45]. It would have been an obvious matter of design choice to change the distance between holes (i.e. the diameter of the fibers in the fabric embodiment) to be smaller in order to catch smaller particles. There would be no surprising effect of having smaller fibers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP

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July 23, 2004

Julian W. Woo

**JULIAN W. WOO
PRIMARY EXAMINER**